IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

GENENTECH, INC. and CITY OF HOPE,

Plaintiffs,

Civ. No. 17-1407- CFC, Consol.

٧.

AMGEN INC.,

Defendant.

MEMORANDUM ORDER

Amgen has moved for leave to amend its First Amended Answer,
Affirmative Defenses, and Counterclaims to add an affirmative defense and
counterclaim that U.S. Patent 8,574,869 ("Kao") is unenforceable because of
inequitable conduct before the United States Patent and Trademark Office
("PTO"). D.I. 507. In Amgen's words: "The inequitable conduct . . . relates to
actions taken at the PTO by Genentech's inventors and prosecuting attorneys—
specifically their deliberate withholding of data and conclusions concerning
Example 8 and Figure 20 of Kao." D.I. 558 at 3.

As a general matter, Rule 15(a) governs the amendment of pleadings before trial. But when, as here, a party seeks to amend a pleading after the scheduling

order's deadline for pleading amendments has passed, the court will apply Rule 16(b) as opposed to Rule 15(a). Eastern Minerals & Chems. Co. v. Mahan, 225 F.3d 330, 340 (3d Cir. 2000). Rule 16(b) requires district courts to impose a schedule and instructs that once the schedule is set, it "may be modified only for good cause and with the judge's consent." FED. R. CIV. P. 16(b)(4) (emphasis added). "Good cause" exists when the party seeking leave to amend exercised reasonable diligence in trying to comply with the scheduling order. See WebXchange Inc. v. Dell Inc., 2010 WL 256547, at *2 (D. Del. Jan. 20, 2010). Thus, "[i]n contrast to Rule 15(a), the good cause standard under Rule 16(b) hinges on diligence of the movant, and not on prejudice to the non-moving party." Id. (internal citation omitted).

Under the then-operative scheduling order, the deadline to file amendments to pleadings was February 22, 2019. *See* D.I. 260. Amgen filed its motion to amend seven months later, on September 20, 2019. D.I. 507.

Amgen concedes that Genentech produced to it in October 2018 and January 2019 three internal Genentech presentations that contained the data that Amgen alleges Genentech deliberately withheld from the PTO. D.I. 508 at 6–7. It argues, however, that "it was not until the depositions" of three witnesses had been completed "in July 2019 that Amgen could plead this [inequitable conduct] defense with sufficient particularity." *Id.* at 13.

Because, by its own admission, Amgen had the ability in July 2019 to plead with particularity the proposed inequitable conduct claim and defense it now seeks to add to the case, I find that Amgen unduly delayed by waiting until September 2019 to seek leave to add that claim and defense to the case.

Because Amgen has failed to show good cause for its delay, IT IS HEREBY ORDERED that its Motion for Leave to Amend Its First Amended Answers, Affirmative Defenses, and Counterclaims (D.I. 507) is DENIED.

Dated: February 12, 2020

UNITED STATES DISTRICT JUDGE